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K994087

SUMMARY OF SAFETY AND EFFECTIVENESS

Sutura™, Inc.

SuperStitch®

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Company: Sutura™, Inc.
17080 Newhope Street
Fountain Valley, CA 92708
Phone: (714) 437-9801
Fax: (714) 437-9806

Company Representative: David B. Barry
Vice President, RA/QA

Date 510(k) Prepared: December 1, 1999

Device Name: SuperStitch® vascular suturing device

Classification Name: Needle, Suturing, Disposable (21 CFR §878.4800)

Product Code: GCJ

Classification: Class II

Devices to which Equivalence is Claimed

Automatic suturing devices are made by various manufacturers. The technological characteristics of the SuperStitch® and accessory Knot Pusher are substantially equivalent to the following devices:

Vascular Stitcher (K963965), CardioThoracic Systems, Inc.
AutoSuture™ Endoscopic Suturing Device (K934738), U.S. Surgical Corporation
AutoSuture Endoscopic Knot Pusher™ (K925149), U.S. Surgical Corporation

Indication for Use:

SuperStitch® is indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. It is not intended for blind vascular closure.

Device Description:

The SuperStitch® device is designed for use with or without an access device (e.g., trocar, sheath, or cannula) depending on the endoscopic technique, for use during

K994087

minimally invasive surgical procedures, or for application directly to a vessel or wound site in an open setting. SuperStitch® applies one nonabsorbable sterile surgical suture.

The knot pusher is comprised of two components: a snare to capture one strand of the suture and a tubular body that is used to advance the tied knot to the surface of the tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2000

Mr. Dave Barry
Vice President, Regulatory Affairs
and Quality Assurance
Sutura™, Inc.
17080 Newhope Street
Fountain Valley, California 92708

Re: K994087
Trade Name: SuperStitch® Vascular Suturing Device
Regulatory Class: II
Product Code: GCJ, KOG, GAW
Dated: December 1, 1999
Received: December 3, 1999

Dear Mr. Barry:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994087

INDICATIONS FOR USE STATEMENT

Sutura™, Inc.

SuperStitch®

510(k) Number: K994087

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Concurrence of CDRH, Office of Drug Evaluation (ODE)

MRD for JSD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994087

Prescription Use YES
(Per 21 CFR 801.109)